DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 30, 2016

Synaptive Medical Inc.
Mr. Cameron Piron
President
101 College Street, Suite 200
Toronto, ON M5G 1L7
Canada

Re: K153281
Trade/Device Name: BrightMatter Guide with SurfaceTrace Registration
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: February 26, 2016
Received: February 29, 2016

Dear Mr. Cameron Piron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153281

Device Name
BrightMatter Guide with SurfaceTrace Registration

Indications for Use *(Describe)*
BrightMatter Guide with SurfaceTrace Registration is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The user should consult the "Accuracy Characterization" section of the User Manual to assess if the accuracy of the system is suitable for their needs.

The system should be operated only by trained personnel such as surgeons and other clinic staff.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

Synaptive Medical Inc.
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President
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Date prepared: March 29, 2016

II. DEVICE

Name of Device: BrightMatter Guide with SurfaceTrace Registration
Common or Usual Name: Stereotaxic instrument
Classification Name: Stereotaxic Instrument (21 CFR 882.4560)
Regulatory Class: II
Product Code: HAW

III. PREDICATE DEVICE

Manufacturer:	Synaptive Medical Inc.
Trade name:	BrightMatter Navigation
510(k) Number:	K142024
Date Cleared:	April 2, 2015

IV. DEVICE DESCRIPTION

The subject device, BrightMatter Guide with SurfaceTrace Registration is a modification of the software component of BrightMatter Navigation system that is presented in K142024. The system is a planning and image guided surgical system that enables computer assisted surgery where use of stereotactic image guidance may be considered appropriate. In particular, the device is suitable for neurosurgical cranial procedures. The planning functionality of the device is provided by an already cleared device, BrightMatter Planning (K140337). The remaining system provides a sequence of discrete workflow activities (or phases) that guide a surgeon through the process of data preparation for the surgical procedure. Then the device aids the surgeon in visualizing the location of the surgical tools relative to clinical images and physical location of the patient.

Following is a summary of steps involved in data preparation and registration of the patient's head position relative to pre-surgical clinical images:

- Importing plan and imaging data
- Reviewing and selecting a previously generated surgical plan
- Optionally fusing (merging or co-registering) additional imaging data
- Registering the clinical images to the patient using either Point registration or SurfaceTrace based registration.

Following steps are provided as visualization tools during the execution of the surgical procedure:

- Aid in visualizing location of the surgical site as planned by the surgeon (using BrightMatter Planning software, K140337)
- For trajectory-centric procedures, help visualize insertion of tracked surgical tools by identifying location of surgical tool's position and orientation relative to clinical images and the surgical plan developed by the surgeon
- Visualize location of tracked surgical tools after the intended target location has been reached
- The purpose of this 510k submission is introduce a new registration methodology using changes that are limited to the software component of the previously cleared system. Key functional components of the system are an optical tracking sub-system, navigated surgical tools, custom software application and an external display. The navigated surgical tools are tracked using single-use passive reflective markers (K033621) that are attached to the surgical tools prior to each surgical procedure.

The surgical display and tracking camera are mounted on an Auxiliary Cart. The computer is housed in a Navigation Cart. These components have been cleared as part of the BrightMatter Navigation system (K142024).

As with many systems in the OR, not all components need to be sterile during use. The only sub-components that come in contact with the patient are the Pointing Tool, Port Reference Tool and Calibration Block. These tools fit in the limited contact duration category. The tools have been cleared as part of the BrightMatter Navigation system (K142024).

V. INDICATION FOR USE

BrightMatter Guide with SurfaceTrace Registration is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The user should consult the "Accuracy Characterization" section of the User Manual to assess if the accuracy of the system is suitable for their needs.

The system should be operated only by trained personnel such as surgeons and other clinic staff.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design comparison summary: Both the subject device and the predicate device, BrightMatter Navigation, help develop a treatment plan. This treatment plan is then used as input to image guided surgery. Both systems track the surgical tools using an optical 3D tracking system and the position and orientation of these tools are displayed relative to the clinical images of the patient. This information is used by the surgeon to guide the surgical instrument(s) to a target location designated by the surgeon. Both systems utilize a software sub-system that is workflow based. Hence, the overall design of the two systems are equivalent. The only difference is that the subject device provides an additional registration method. The predicate device provides point registration only. The subject device provides Point registration and SurfaceTrace Registration.

Technology comparison: The BrightMatter Guide System with SurfaceTrace Registration is similar to the predicate device, BrightMatter Navigation System V1.0. Both systems help develop a treatment plan. The subject device incorporates an additional means of registering the clinical images to patient's anatomy while maintaining all other functionality present in the predicate device. Further, the new registration method is provided as an additional method for performing registration and does not replace the, already cleared, point registration method.

The subject device is a modification of the software component of previously cleared medical device, BrightMatter Navigation (K142024), and the software component is intended to be used in conjunction with remaining components of the cleared device.

The accuracy of the subject device when using SurfaceTrace Registration was characterized using an accuracy measurement phantom that was registered using SurfaceTrace method. The system accuracy was measured using the navigated tools (Pointer Tool and the Port Reference Tool). Mean positional error was measured to be less than 2 mm and mean angular error was measured to be less than 2 degrees for both the tools. This performance was observed at the center and at the boundaries of the field of view of the tracking camera. System accuracy did not deteriorate when tracking multiple tools.

VII. PERFORMANCE DATA

The following testing was conducted on BrightMatter Guide with SurfaceTrace Registration:

- Characterization of system accuracy using an accuracy measurement phantom of similar volume to an adult head. The values of the ground truth data from the accuracy phantom were obtained using a Coordinate Measurement Machine (CMM). Positional error was measured to be less than 2 mm and angular error was measured to be less than 2 degrees at all locations within the tracking volume.
- Characterization of system display latency by confirming that it is comparable to that of the predicate device.
- Software verification and validation testing for each requirement specification.

- System integration testing using anatomical phantoms.

The following quality assurance measures were applied during development of the software component of the system:

- Software Development Life Cycle
- Software Risk Assessment.
- Risk Assessment of Off-the-Shelf (OTS) Software.
- Software Configuration Management and Version Control.
- Software issue tracking and resolution.

Design Validation: Design validation was performed using BrightMatter Guide with SurfaceTrace Registration in simulated use settings with intended users. The results demonstrate that BrightMatter Guide with SurfaceTrace Registration is substantially equivalent to the predicate device.

Clinical Testing: This technology is not new, therefore a clinical study was not considered necessary prior to release.

VIII. CONCLUSIONS

The non-clinical data support the substantial equivalence of the subject device to the predicate device.